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6 Key Elements of Successful Drug & Device Development in Europe.

"What's the best way to get my product approved and marketed in Europe?"

Emerging pharma, biotech and device executives often ask variations of the same question, "What's the best way to get my product approved and marketed?" Of course, each of these executives often bring his or her own specific expertise the project: one might be a clinical physician, another a Ph.D. scientist, another an intellectual property attorney, etc. Because no one CEO has all the skills necessary to successfully launch a drug, these companies bring in expertise from outside organizations.

Often, an emerging company may need to select the best candidate from a number of possible products and indications in its portfolio. Several elements must be considered when narrowing down multiple options to one or two.

There are six interconnected development elements that must be considered and successfully executed in order to bring a drug or device to market. As a memory aid, use the acronym **PRIMES**: **P**roduction, **R**egulatory, **I**nvestment, **M**arketing, **E**xclusivity and **S**cience. The dictionary definition of primes is "To prepare someone for a situation or task, typically by supplying relevant information," which seems appropriate.

Each element typically impacts some or all the other elements. For example, if an organization is considering orphan drug exclusivity for their product, that will impact production (small volume), regulatory (application for Orphan Drug Designation), investment (enhanced by ODD), marketing (to a small, defined segment, perhaps with advocates) and science (efficacy must be demonstrated on a smaller patient sample).

As you move forward in your development process, keep **PRIMES** in mind to ensure that you are considering all the elements that are necessary for success.

Production: Can we manufacture the product?

Most emerging companies use the services of a Contract Manufacturing Organization (CMO). Some of these organizations also assist in product development and are referred to as CDMOs. In selecting a CMO, make sure that it is familiar with your product type and route of administration. Volume is also important; your forecasted output, should match the capacity of the CMO.

Regulatory: What is the path to Agency (EMA, MHRA, etc.) approval?

Since the objective of the drug development process is Agency approval, the regulatory plan is of paramount importance, defining key meetings and submissions to EMA/MHRA, while integrating nonclinical and clinical development plans. A variety of scientific disciplines are necessary to develop and execute the plan: nonclinical/toxicology, medical/clinical, Chemistry, Manufacturing, and Controls (CMC) and biopharmaceutics/pharmacology. ProPharma refers to this key document as a "Roadmap to Approval." It is essential that you have an optimal plan before presenting to Regulatory Agencies or investors. Inevitably the plan will change during development. A wise general once said "Plans are useless, but planning is indispensable."

Investment: How will I fund the project?

To achieve each milestone in the drug/development process, you will make an investment which will diminish your risk and increase the value of your asset. At each successful milestone completion, investment and value increase as risk diminishes. Early funding is usually provided by grants or individual investors. Private equity firms typically wait until Phase 2 of development, when risk is lower and potential rewards are greater.

Marketing: What be the commercial value of the product?

Early in the process, it is important to get a sense of the commercial value of the product. This is particularly important if you are trying to select one product and/or indication from multiple possibilities. A standard is often selected for comparison purposes. e.g., mature annual sales five years after product launch. Numerous variables effect the commercial value including exclusivity/patent protection, disease prevalence; competing products; unmet need, etc. Early in the process you will want to contact one of the many firms that specializes in commercialization of drugs and devices.

Exclusivity: Do I have patent or other protection?

It is critical to get as much patent protection as possible early in the development process, engaging an intellectual property attorney that specializes in drugs or devices.

The ultimate value of your product will be based on its patent protection and other exclusivity afforded by Regulatory Agencies. A helpful summary on exclusivity follows a general 8+2+1 Rule, defined below:

8 years of Data Exclusivity	Generic application cannot cross-refer to your dossier
+ 2 years of Market Exclusivity	Generic competitor cannot launch
+ 1 year Exclusivity	If a new indication is subsequently approved that brings significant therapeutic benefit.

Note that orphan products get 10 years of marketing exclusivity in that orphan indication, which can be extended by an additional 2 years if a Paediatric Investigation Plan (PIP) is completed as agreed within the 10-year exclusivity period.

Science: Will the product work?

Of course, this is the key question, and the reason clinical trials are conducted. The hybrid application under Article 10(3) of Directive 2001/83/EC enables sponsors to use prior approvals and/or scientific literature to make the case for safety and efficacy, a great benefit considering that clinical trial are expensive.